

Appl. No.  
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CLEAN SET

3. A method according to claim 21 comprising an emitted dose of 80 - 100% w/w.

4. A method according to claim 21 comprising a fraction of particles depositing on stage 4 and the filter of a multistage liquid impinger of at least 60% w/w.

5. A method according to claim 21 wherein the lipid comprises a phospholipid selected from the group consisting of dipalmitoylphosphatidylcholine, disteroylphosphatidylcholine, diarachidoylphosphatidylcholine dibehenoylphosphatidylcholine, diphosphatidyl glycerol, short-chain phosphatidylcholines, long-chain saturated phosphatidylethanolamines, long-chain saturated phosphatidylserines, long-chain saturated phosphatidylglycerols, and long-chain saturated phosphatidylinositols.

6. A method according to claim 21 wherein the inhaler comprises a resistance of less than  $0.60 \text{ (cmH}_2\text{O)}^{1/2} / \text{L min}^{-1}$ .

7. A method according to claim 6 wherein the inhaler comprises a resistance within the range of  $0.01 - 0.30 \text{ (cmH}_2\text{O)}^{1/2} / \text{L min}^{-1}$

8. A method of claim 21 wherein the inhalation flow rate is less than about 90 L/min.

9. A method of claim 8 wherein the inhalation flow rate is within the range of about 10 - 60 L/min.

10. A method of claim 9 wherein the inhalation flow rate is within the range of 12 - 45 L/min.

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11. A method of claim 21 wherein the lung deposition is greater than 25% w/w of the nominal dose.

12. A method according to claim 21 wherein the lung deposition is about 30 - 60% w/w of the nominal dose.

14. A method according to claim 21 wherein the drug is selected from the group consisting of budesonide, tobramycin sulfate, leuprolide acetate, Amphotericin B, and parathyroid hormone.

15. A method of claim 21 wherein the powder comprises hollow porous microparticles.

16. A method for inhalation of a dry powder drug comprising:  
providing a dry powder drug composition comprising a hydrophobic active agent, said composition comprising particles comprising a lipid matrix and a particle size of 1-30 microns, mass median aerodynamic diameter of less than 5 microns, and bulk density of less than 0.5 g/cm<sup>3</sup>;

loading the composition into a passive dry powder inhaler;  
inhaling the drug composition from the inhaler in order to achieve a Tmax within 15 minutes of the inhalation.

17. A method according to claim 16 wherein the active agent is amphotericin B.

18. A method according to claim 16 wherein the active agent is budesonide.

19. A method according to claim 18 wherein T max is achieved within 10 minutes of the inhalation.

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20. A method according to claim 16 wherein the lipid comprises a phospholipid selected from the group consisting of dipalmitoylphosphatidylcholine, disteroylphosphatidylcholine, diarachidoylphosphatidylcholine dibehenoylphosphatidylcholine, diphosphatidyl glycerol, short-chain phosphatidylcholines, long-chain saturated phosphatidylethanolamines, long-chain saturated phosphatidylserines, long-chain saturated phosphatidylglycerols, and long-chain saturated phosphatidylinositols.

21. A method for inhalation of a dry powder drug comprising:

administering a dry powder drug composition comprising particles comprising a phospholipid matrix and a particle size of 1-30 microns, mass median aerodynamic diameter of less than 5 microns, and bulk density of less than 0.5 g/cm<sup>3</sup> from a passive dry powder inhaler wherein the emitted dose of said composition exiting from said passive dry powder inhaler after a single inspiratory effort is at least 60% w/w and is substantially independent over an inhalation flow rate of 20-90 l/min and device resistance of 0.04-0.20(cmH<sub>2</sub>O)<sup>1/2</sup> /L min<sup>-1</sup>.

22. The method of claim 21 wherein at least 5 milligrams of drug are administered per inhalation.

23. The method of claim 22 wherein at least 10 milligrams of drug are administered per inhalation.

24. The method of claim 23 wherein at least 20 milligrams of drug are administered per inhalation.

25. The method of claim 24 wherein at least 25 milligrams of drug are administered per inhalation.

26. The powder of claim 21 wherein said drug is selected from the group consisting of antiallergics, bronchodilators, pulmonary lung surfactants, analgesics, antibiotics, antiinfectives, leukotriene inhibitors or antagonists, antihistamines, antiinflammatories, antineoplastics, anticholinergics, anesthetics, anti-tuberculars, imaging agents, cardiovascular

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agents, enzymes, steroids, DNA, RNA, viral vectors, antisense agents, proteins, peptides and combinations thereof.

27. The powder of claim 21 wherein said drug is selected from the group consisting of nicotine, fentanyl, morphine, lung surfactant, parathyroid hormone, leuprolide, interferon, goserelin, and growth hormones.

28. A method of delivering a therapeutic dose of a bioactive agent to the pulmonary system in a single breath, comprising:

administering particles comprising a bioactive agent from a passive dry powder inhaler wherein the emitted dose of said particles exiting from said inhaler is at least 80% w/w after a single inspiratory effort.

29. A method of delivering a therapeutic dose of a bioactive agent to the pulmonary system in a single breath, comprising:

administering particles comprising a bioactive agent from a passive dry powder inhaler wherein the fraction of particles having a geometric diameter of less than 3.3 microns administered from said inhaler is at least 35% w/w after a single inspiratory effort.